Nephrol Dial Transplant (2001) 16: 2194–2200

Nephrology Dialysis Transplantation

Original Article

A prospective study of complications associated with cuffed, tunnelled haemodialysis catheters†

Mark A. Little[1], Aisling O'Riordan[1], Brian Lucey[2], Michael Farrell[2], Michael Lee[2], Peter J. Conlon[1] and J. Joseph Walshe[1]

[1]Department of Nephrology and Transplantation and [2]Department of Interventional Radiology, Beaumont Hospital, Dublin, Ireland

Abstract

Background. Despite the US Dialysis Outcome Quality Initiative (DOQI) guidelines, for various reasons, increasing numbers of end-stage renal disease patients are becoming dependent on cuffed haemodialysis catheters (HCs) for chronic haemodialysis access. Their use is complicated by frequent failure due to thrombosis and catheter-related sepsis. In our unit, all HCs are put in place by the radiology department.

Methods. In a prospective study we looked at the outcome of all HCs over a three-year period, during which time 573 consecutive HCs were placed in 336 patients. Each line was followed individually until it was removed or until the end of the study.

Results. In a survival analysis of those HCs removed following HC failure, HC half-life was 312 days and one-year HC survival was 47.5%. The most frequent indications for HC removal were non-function (36.6%), clinical suspicion of line sepsis (16.4%) and patient death (14.4%). Using a Cox proportional hazards model, catheter number in a given patient and the presence of diabetes mellitus were found to be independent predictors of HC failure. The total incidence of HC-related sepsis was 1.3 episodes/1000 catheter days. The probability of developing bacteraemic HC-related sepsis was 27.5% at one year.

Conclusions. Less than half of the HCs were removed electively because of availability of a more permanent mode of renal replacement, thereby illustrating the level of dependence that has developed on them as permanent access. Consequently, their limitations (infection and malfunction) are placing an ever increasing burden on the healthcare services.

Keywords: cuffed haemodialysis catheter; infection; survival; thrombosis

Correspondence and offprint requests to: Prof. J. Joseph Walshe, Department of Nephrology and Transplantation, Beaumont Hospital, Dublin 9, Ireland. Email: joseph.walshe@beaumont.ie

†Presented in part at XXXVI ERA-EDTA Annual Congress, Madrid, September 1999.

Introduction

Tunnelled haemodialysis catheters (HCs) were initially developed as a means of short to medium term haemodialysis access while a more permanent form of access, such as an arteriovenous fistula (AVF), was maturing. The first report demonstrating their effectiveness in this setting was published by Schwab *et al.* in 1988 [1]. The technique gained rapidly in popularity to the extent that many nephrologists chose tunnelled HCs over traditional non-cuffed HCs, even for patients with acute renal failure.

In the latter part of the 1990s, however, there has been a shift towards an increased reliance upon these semi-permanent catheters as a means of permanent access in patients on chronic haemodialysis [2]. The reasons for this include ease of insertion, an increasing proportion of elderly and diabetic patients with vessels unsuitable for AVF and patient choice (there are no needles when a HC is used). In addition, the expedience of using a cuffed HC has contributed to complacency among nurses and doctors; opening a HC port is easier than needling a fistula and inserting a line is often easier than arranging for an AVF or synthetic graft.

However, with these catheters it is frequently difficult to obtain adequate blood flows [3], there is a higher incidence of thrombosis [4], and it is often necessary to reverse the ports, with a consequent increase in recirculation [5]. In addition, the patient is prone to more episodes of bacteraemia [6] with the concomitant increased use of broad-spectrum antibiotics [7]. The latter, in turn, has contributed to the emergence of vancomycin resistant *Enterococcus* and *Staphylococcus epidermidis* as well as the widespread flourishing of methicillin resistant *S. aureus* (MRSA) [7] and *Clostridium difficile* [8]. With increased dependence on HCs these complications are placing an increasing burden on dialysis healthcare providers. The scale of this problem and the factors associated with HC failure are, however, unknown. Therefore, we undertook to examine, using a prospective design,

all tunnelled HCs inserted over a three-year period, with focus on HC-related sepsis (CRS).

Subjects and methods

Study design

At Beaumont Hospital the Interventional Radiology Department places tunnelled HCs with the aid of sonography and fluoroscopy. Four interventional radiologists inserted all the HCs during the study period. The choice of HC and site of insertion was at the discretion of the radiologist and attending nephrologist but, in the absence of mitigating factors, the site of first choice was the right internal jugular vein. The subclavian vein was used only after attempting to cannulate the internal jugular veins. Prophylactic antibiotics were not employed at the time of insertion. During the time period under study, between 50% and 60% of patients on chronic haemodialysis at this institution were dependent on cuffed, tunnelled HCs for dialysis access. The study was performed at a single dialysis centre. Only trained dialysis nurses, utilizing sterile gloves and povidone iodine disinfection, opened the HC. After each use the HC was locked with heparin 1000 units/ml in a volume equal to the luminal volume of the HC. Patients were routinely screened for *S. aureus* carriage and received topical mupirocin if so affected. Continuous low-dose warfarin was not employed as prophylaxis against HC thrombosis.

Over a three-year period (10/95–10/98), data on all consecutive HCs were entered prospectively into a logbook at the time of insertion. Some 577 HCs were placed, of which four were excluded because the indication for placement was the administration of oncology drugs. Thus, 573 HCs in 336 patients remained for analysis. Each HC was followed separately.

Catheters were removed if they were no longer needed (AVF maturation, CAPD catheter ready, death of patient, renal transplantation or recovery of native function) or if a significant complication was encountered (catheter non-function or suspected catheter-related sepsis). Catheters were followed until one of these end-points or the date 31/12/98 was reached. Catheters were deemed to have 'failed' if they were removed because of a complication. Survival data in these catheters were used to assess factors potentially associated with catheter failure.

Data were recorded on the reason for HC removal, any episodes of fever or clinically suspected CRS, microbiological culture results and antibiotic usage. Culture data were obtained by 'flagging' patients with HC on the microbiological computer system. For each clinically relevant isolate the profile of antibiotic resistance was recorded.

Definitions and management of HC-related sepsis

A patient developing fever with a HC *in situ* was considered to potentially have CRS. In all cases blood was aspirated in a sterile fashion from each port of the HC and from a peripheral vein for culture. Such patients were also assessed clinically, urine was obtained for culture, a chest X-ray was performed and further microbiological tests were performed as indicated. In the absence of signs of severe infection (e.g. hypotension, altered mental state, erythema and tenderness along the subcutaneous track), a trial of intravenous vancomycin and gentamicin, administered via the HC, was employed. If either severe infection was present or 48 h of antibiotic therapy failed to result in defervescence, the HC was removed and the tip was cultured. A non-quantitative roll technique was used when culturing HC tips. Each isolate was tested against a standard battery of antibiotics to determine the resistance profile. In the case of infection in the subcutaneous tunnel, a 2-week trial of oral antibiotics was undertaken for mild infection. If the infection failed to improve after this time, or if severe infection was present (e.g. pus appearing at the exit site), the HC was removed and the tip cultured.

Siegman-Igra *et al*. recently performed a meta-analysis of 22 studies looking at the diagnosis of CRS in the clinical setting [9]. On the basis of this we adopted the following definition of CRS: *definite CRS*, clinical evidence of sepsis with isolation of the same organism from peripheral and central blood and/or a line segment with no other source of sepsis evident; *probable CRS*, clinical evidence of sepsis with isolation of a common skin organism from a blood culture, no other source of sepsis evident and defervescence after removal of the HC; and *possible CRS*, clinical evidence of sepsis with negative cultures, no other source of sepsis evident and defervescence after removal of the HC. In many of these cases the patient had received antibiotics before the culture was taken.

CRS occurring less than one week after HC insertion was considered to be related to HC insertion and termed primary CRS.

Statistical methods

Using SPSS 9.0 software, comparisons of binary and categorical factors with the removal of a HC due to complication were made using likelihood ratio chi-square and Wilcoxon rank-sum statistics as appropriate. Kaplan–Meier survival curves were constructed for HCs that were removed because of a complication. The data were censored in the event of elective HC removal or the HC remaining *in situ* at the end of the study. Curves were constructed for the following factors: age, gender, diagnosis, catheter type and location, catheter number for each patient (i.e. first, second, third, etc.) and presence of diabetes mellitus (DM). The log rank test was used to identify factors associated with catheter failure at a P value of <0.1. A Cox-regression model was developed from these factors using a forward stepwise conditional technique to identify factors independently associated with catheter failure. Assumption of proportionality was tested for each variable. In addition, Kaplan–Meier curves were constructed to estimate the risk of bacteraemic CRS. The Mantel–Haenszel test was used to estimate the odds ratio of HC failure and 95% confidence intervals (CI).

Results

Patient population

Of the 336 patients studied, 211 (62.8%) were male and the mean age was 57.8 years (95% CI: 55.9 to 59.6). The population was elderly with 145 (43.2%) of patients $\geqslant 65$ years. Compared with those dialysed using AVF or PTFE graft, these patients tended to be older and many had had previous attempts at permanent access. Therefore, the general state of their vasculature was inherently worse. The causes of

Table 1. Causes of ESRD in study population, $n=336$

	n	%
Chronic glomerulonephritis	77	22.9
Chronic pyelonephritis	35	10.4
Diabetes mellitus	30	8.9
Hypertension	25	7.4
APCKD	23	6.9
Renovascular disease	20	5.9
Interstitial nephritis	9	2.7
Obstructive uropathy	8	2.4
Multiple myeloma	7	2.1
Other	21	6.3
Unknown	81	24.1

end-stage renal disease (ESRD) are summarized in Table 1. The three commonest causes of ESRD encountered were chronic glomerulonephritis (30.2%), chronic pyelonephritis (13.7%) and DM (11.8%). In patients with non-diabetic renal disease DM was present as a co-morbid condition in 8 patients, giving a total prevalence of DM of 15.3%. In 25 patients the HC was inserted in the setting of acute renal failure from which recovery was expected; in all remaining patients, the HC was placed in the setting of established end-stage renal failure. Of these 548 HCs, 210 were inserted to replace a HC that had failed previously. The site of HC placement was right internal jugular (RIJ) in 418 (72.9%), left internal jugular (LIJ) in 94 (16.4%), right subclavian (RSC) in 42 (7.4%) and left subclavian (LSC) in 17 (3.0%). Two HCs (0.3%) were placed in a trans-lumbar position. The HC type was Permcath™ (Quinton instruments Co., Seattle, WA) in 354 (61.8%), Vascath Soft Cell™ (Bard Instrument Co., Toronto, Canada) in 170 (29.7%) and Hickman™ (Bard Instrument Co., Toronto, Canada) in 49 (8.6%).

HC survival

The mean duration of follow-up per HC was 157.1 days (range 2–1091) with 124 HCs (21.8%) still functioning at the end of the study. There was a total of 89 216 catheter days (2933 catheter months) of follow-up. The mean duration of HC use in those removed was 128.1 days (95% CI: 111.4 to 144.8). The reasons for removal are summarized in Table 2. The most common indications for HC removal were non-function in 163 (36.3% of those removed), clinical suspicion of line sepsis in 73 (16.4%) and death of the patient with a functioning HC in 64 (14.4%). Catheter failure (either due to HC non-function or clinical suspicion of line sepsis) was the reason for removal in 236 (52.6%) cases. In all of these, the patient was reliant upon the HC for dialysis access and it was therefore necessary to replace it with a new cuffed HC. Thus, less than half of the HCs were removed as a result of not being needed anymore (i.e. because of AVF maturation, commencement of CAPD, renal transplantation, recovery of renal function or death with a functioning HC).

Table 2. Indications for HC removal, $n=449$

Reason for removal	*n*	%
HC non-function	163	36.3
Clinical suspicion of CRS	73	16.3
Patient death	64	14.3
Maturation of AVF/PTFE graft	63	14.0
Renal transplant	46	10.2
Commenced CAPD	21	4.7
Recovered native function	19	4.2

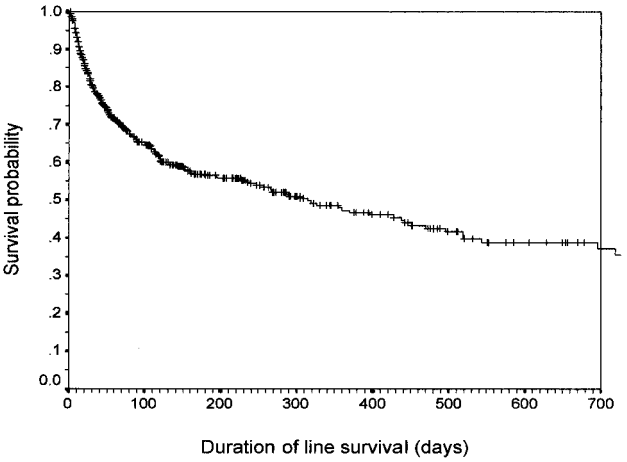

Fig. 1. Kaplan–Meier survival curve illustrating HC survival after censoring HCs still *in situ* at the end of the study or removed electively (+); HC half-life was 312 days and one-year HC survival was 47.5%.

In an analysis of those HCs removed following HC failure, actuarial HC half-life was 312 days, one year HC survival was 47.5% (Figure 1) and median HC survival time was 312 days (95% CI: 208 to 422). After univariate analysis (Table 3), the presence of DM, HC number, HC location and gender were associated with HC failure. The unadjusted survival probability according to HC location is summarized in Figure 2. There was no association between the type of HC and HC failure. Figure 3 illustrates HC survival according to whether they were the first, second, third or subsequent HCs. There was little difference in survival between the first three HCs. However, a dramatic decline in HC survival was evident for the fourth and subsequent HCs (actuarial half-life 75 days, one-year HC survival 13.9%, $P<0.001$ by log rank test). Using Cox proportional hazards analysis (Table 4), the factors found to be independently associated with HC failure were the HC number ($P<0.001$) and the presence of DM ($P<0.05$).

HC-related sepsis

The data concerning CRS are summarized in Table 5. As shown, considering the aggregate of the 3 groups, there was one episode of CRS/25.6 patient months or 1.3 episodes/1000 catheter days. Twenty-three of the episodes of CRS (24.0%) occurred less than one

week after HC insertion. The actuarial probability of freedom from bacteraemic CRS is summarized in Figure 4. The risk of CRS was 27.5% at one year. There were four deaths directly attributable to HC-related sepsis. In addition, there were two cases of osteomyelitis, one case of septic arthritis and two cases of infective endocarditis.

A breakdown of the organisms identified is given in Figure 5. The overwhelming majority of organisms were staphylococcal (68.6% *S. aureus*, 27.5% Coagulase negative *Staphylococcus*). There were 19 isolates of MRSA (incidence of MRSA CRS = 0.21/1000 HC days, prevalence = 18.6% of all isolates). There were no instances of vancomycin resistance.

Table 3. Univariate analysis of factors associated with HC failure

	Removed for complication ($n=236$)	Remained functioning ($n=337$)	P value
Catheter number			
First	133 (36.6%)	230 (63.4%)	<0.001
Second	39 (36.1%)	69 (63.9%)	
Third	20 (50.0%)	20 (50.0%)	
Fourth or greater	44 (71.0%)	18 (29.0%)	
Gender			
Male	126 (37.6%)	209 (62.4%)	0.039
Female	110 (46.2%)	128 (53.8%)	
Location			
RIJ	160 (38.3%)	258 (61.7%)	0.021
LIJ	40 (42.6%)	54 (57.4%)	
RSC	25 (56.8%)	19 (43.2%)	
LSC	11 (64.7%)	6 (35.3%)	
Type			
Soft Cell	70 (41.1%)	100 (58.9%)	0.855
Permcath	144 (40.7%)	210 (59.3%)	
Hickman	22 (44.9%)	27 (55.1%)	
Diabetes			
Yes	41 (53.9%)	35 (46.1%)	0.014
No	195 (38.9%)	306 (61.1%)	
Age quartile			
1	67 (48.6%)	71 (51.4%)	0.146
2	56 (42.4%)	76 (57.6%)	
3	53 (39.8%)	80 (60.2%)	
4	48 (35.0%)	89 (65.0%)	

Discussion

In this prospective study, we report on the outcome of a large series of consecutive cuffed HCs and demonstrated that, in an institution with a high rate of HC use, 52% were removed as a result of either suspected HC-associated sepsis or HC non-function. In all of these cases it was necessary to replace the HC in a semi-urgent fashion, thereby illustrating the degree of dependency on these access devices that has developed. Their role has expanded to the extent that many patients are dependent upon them for long-term haemodialysis access. Of those used as 'permanent' access, 47.5% were still functioning at one year, the most frequent reason for HC failure being malfunction. The presence of DM and HC number were identified as independent predictors of HC failure. Of note, the make and type of HC had no effect on HC survival time.

With 2933 patient-months of follow-up, we believe that our study provides important information on the longevity of cuffed HCs. The most powerful predictor of HC failure was whether or not the patient had required a semi-permanent HC previously. Individual HC longevity declined successively each time the HC was replaced in a given patient. This finding is intuitive but has not been reported before. The most likely reason for it is the fact that the host vein is structurally altered after an episode of CRS or HC thrombosis. Indeed, merely placing a HC into a central vein can damage that vein, occasionally resulting in luminal obliteration. Therefore, with each episode of HC failure it becomes progressively more difficult to find a 'pristine' vein and one is forced to place HCs in veins

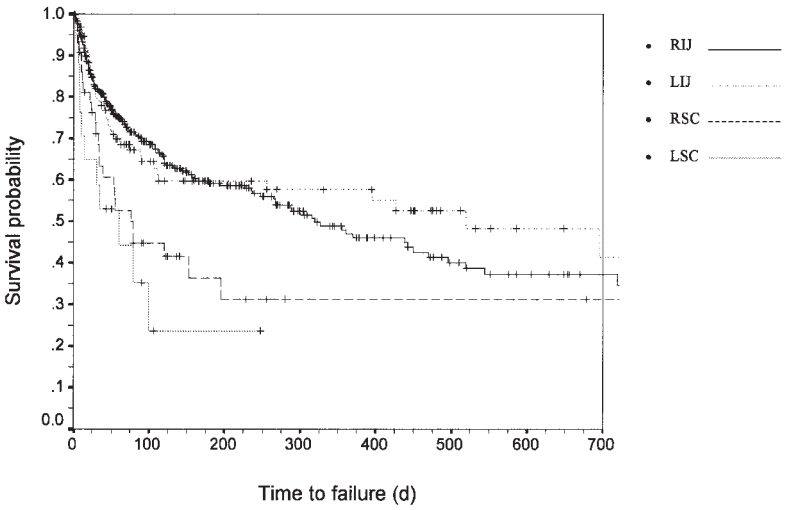

Fig. 2. Kaplan–Meier plot illustrating the unadjusted survival probability of HCs according to the site of HC insertion ($P<0.001$ by log rank test).

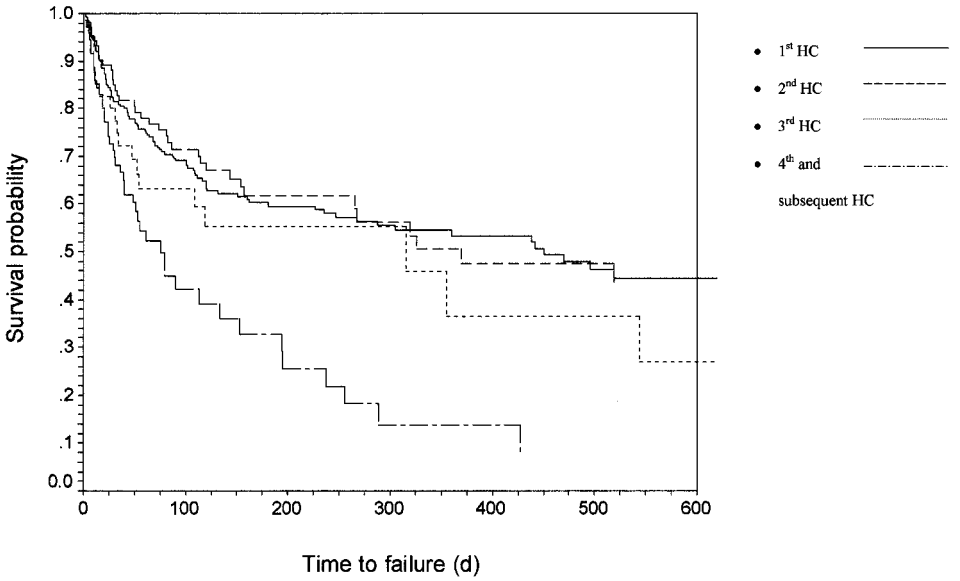

Fig. 3. Kaplan–Meier plot illustrating HC survival for first, second, third and subsequent HCs. $P<0.001$ for trend by log rank test.

Table 4. Factors found to be independently associated with catheter failure by Cox proportional hazards modelling

Variable	Odds ratio (95% CI)	*P* value
Catheter number (First *vs* subsequent)	0.62 (0.44–0.87)	0.001
Presence of DM (Yes *vs* no)	1.84 (1.1–2.9)	0.02

Table 5. Incidence of CRS

	n	Episodes per 1000 catheter days	Months per episode of CRS
Definite CRS	59	0.66	50.4
Probable CRS	38	0.43	78.3
Possible CRS	19	0.21	156.5
Total	116	1.30	25.6

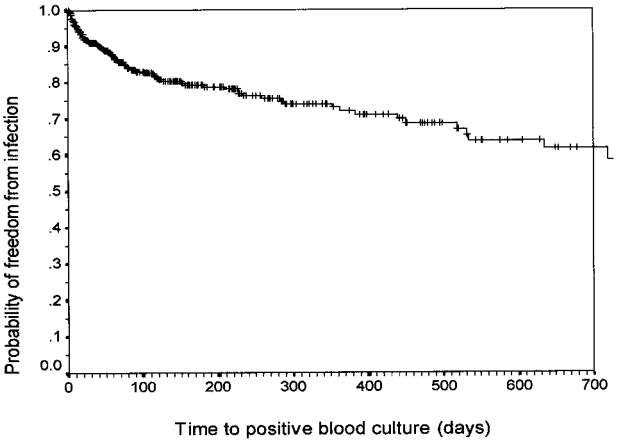

Fig. 4. Kaplan–Meier plot illustrating the actuarial probability of definite or probable CRS (i.e. associated with a positive blood culture). The probability of definite or probable CRS was 9.1% after one month, 21.0% after 6 months and 27.5% after 1 year.

that are less than ideal. It is not surprising that the longevity of these HCs suffers.

In a recent study by Canaud *et al.* [10], median HC survival was reported as 2.5 years with a cumulative incidence of HC failure of only 7.6% at 4 years. The patients were felt to represent an elderly cohort with a mean age 58.4 years and 46.6% of patients >65 years, figures that are almost identical to our patient population. This paper concluded with the assertion that cuffed HC were an excellent vascular access alternative for elderly patients. However, the study excluded HC that functioned for <90 days and those that were inserted into the subclavian vein. We, on the other hand, included all HCs and found a significantly shorter HC survival ($T_{\frac{1}{2}}=10.5$ months) and a much

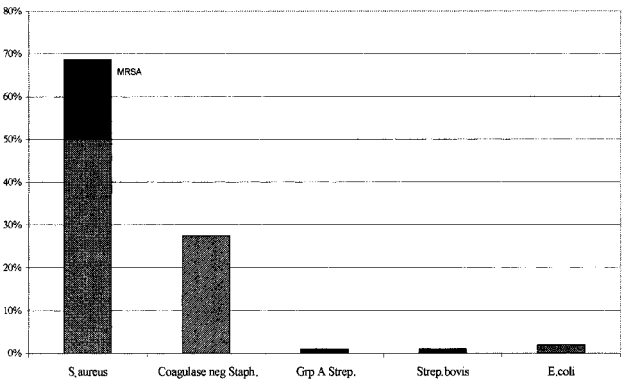

Fig. 5. Organisms responsible for CRS (MRSA).

Table 6. Summary of previously published studies quoting the rate of HC-related sepsis

Authors	Year	HC-related sepsis rate (episodes/1000 HC days)	Comments
Almirall J [11]	1989	0.7 (septicaemia)	$n=53$; 55% of HCs were colonized on removal
Moss AH [4]	1990	0.69 (bacteraemia)	$n=168$; HCs used <30 days excluded
Mosquera DA [12]	1992	3.4 (septicaemia)	$n=64$
Marr KA [6]	1997	3.9	$n=102$
Prabhu PN [13]	1997	2.9	$n=82$; restricted to Tesio catheters
Saad TF [14]	1999	5.5	$n=101$; defined as positive blood culture with features of sepsis
Beathard GA [15]	1999	3.4	$n=827$; defined as positive blood culture with features of sepsis
Little MA	2000	1.3[a]	$n=573$

[a] 0.66 (definite) + 0.43 (probable) + 0.21 (possible).

higher incidence of both HC failure and sepsis. The site of first choice in all of our patients was the right internal jugular vein. It was only when this site was exhausted that alternative sites were considered. Only patients with recurrent HC failure received subclavian HCs; consequently, exclusion of these patients would markedly overestimate HC longevity. Moss *et al.* performed a study with a similar design to ours in the late 1980s [4], when cuffed HC use was in its infancy. One-year HC survival of 168 HCs was reported as 65% and median HC survival was 18.5 months compared to respective figures of 47.5% and 10.3 months in our study. However, HCs functioning for <30 days were excluded, thus again potentially over-estimating HC survival. The most striking contrast with our study was the finding that only 15% of HCs were removed because of HC malfunction or sepsis as compared to 52% in our study. Most HCs were removed when a permanent access became available for use in contrast to the contemporary use of cuffed catheters as permanent accesses.

The frequency of HC-related sepsis in our study (total: 1.3 episodes/1000 catheter days; definite: 0.66 episodes/1000 catheter days) was roughly comparable to previously reported data (Table 6). Much of the variation in reported frequencies is due to the somewhat arbitrary definition of HC-related sepsis, something we attempted to rigorously define in advance. Most studies have reported frequencies of between 3 and 5/1000 HC days. In general, only episodes associated with positive blood cultures were included in these studies. Employing this method, the respective incidence in our study was 1.09/1000 HC days. It is unlikely that this lower incidence was due to an under-reporting of blood cultures as all haemodialysis patients were 'flagged' on the microbiology computer system. The threshold for obtaining blood cultures at our institution is low; all patients with fever or general malaise are cultured so this is unlikely to be a factor in the low incidence rate. We were also at pains to exclude alternative sources of sepsis such as the urinary tract or lung. Previous studies reported higher frequencies of Gram-negative organisms causing HC-related sepsis. For example, Beathard's study [15] reported that Gram-negative organisms were present in 33.3% of cases compared to <2% in our study. It is possible that we have been more rigorous in excluding extra-catheter infection. This may explain the difference between this study and previous reports documenting a relatively high frequency of CRS.

Most centres describe AVF patency rates of 60–70% at one year and 50–60% at two years [16]. There is no doubt that they are superior to cuffed catheters for long-term dialysis access and this is reflected in the National Kidney Foundation–Dialysis Outcome Quality Initiative guidelines [17]. Despite this, an ever-expanding population of dialysis patients at our institution and elsewhere is coming to rely upon HCs, thus exposing their limitations. The advancing age of patients and the increasing proportion of diabetics entering the dialysis programme certainly contribute to this phenomenon. However, the logistic ease of HC insertion by a dedicated interventional radiology department when compared to the difficulties associated with the successful creation of an AVF certainly contributes also. These physician-centred barriers, as well as nursing and patient-centred barriers, need to be overcome if the dialysis patient is to benefit ultimately.

Acknowledgements. The authors gratefully acknowledge the assistance of Mr John Duncan in statistical analysis and Dr Nuala O'Connell in providing microbiological information.

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Received for publication: 22.12.00
Accepted for publication: 29.5.01